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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,301	09/19/2003	Amanda April Hartley	12361-15US JEL	1515

20988 7590 01/26/2005

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EXAMINER

STRAIGHTIFF, MICHAEL PAUL

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/666,301

**Applicant(s)**HARTLEY ET AL. EX**Examiner**

Michael P. Straighttiff

**Art Unit**

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/7/04, 6/28/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-9, 12-15, 20-25, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,545,200 to West et al.

- a. In regard to Claim 1, West et al. disclose “[A] device for creating a perforation in material within a patient comprising: an elongate member having a proximal distal region capable of adopting a curved shape” (See West et al., Figure 4, Reference 22; See also Column 8, Lines 22-23), and “a functional tip at the distal region for delivering energy to create the perforation in the material” (See West et al., Figure 4, Reference 34; See also Column 8, Lines 24-27). The intended use/functional language “wherein when the functional tip advances through the material, the distal region adopts a curved shape to direct the functional tip in a desired direction” carries limited patentable weight in the absence of any distinguishing features. West et al. clearly disclose the claimed structure and is considered inherently capable of performing the intended use.
- b. In regard to Claim 3, West et al. further disclose “wherein the curved shape is defined by a radial arc” (See West et al., Figures 3A and 3B).

- c. In regard to Claim 4, West et al. further disclose “wherein the proximal region comprises a marking indicative of the orientation of the curved shape” (See West et al., Figure 4, References 40, 42, and 44; See also Column 8, Lines 29-32).
- d. In regard to Claim 5, see Claim 1 Rejection. The preamble language “[A] device for creating a perforation in a heart septum” and the intended use/functional language “wherein when the functional tip advances through the septum, the distal region adopts a curved shape to direct the functional tip in a desired direction” carries limited patentable weight in the absence of any distinguishing structure. West et al. clearly discloses the claimed structure and is considered inherently capable of performing the intended use.
- e. In regard to Claim 6, West et al. further disclose “wherein the curved shape is defined by a radial arc” (See West et al., Figures 3A and 3B).
- f. In regard to Claim 9, West et al. further disclose “wherein the proximal region comprises a marking indicative of an orientation of the curved shape” (See West et al., Figure 4, References 40, 42, and 44; See also Column 8, Lines 29-32).
- g. In regard to Claim 12, West et al. further disclose “wherein the energy is at least one form of energy selected from a group consisting of: electrical current; microwave; ultrasound; mechanical; and laser” (See West et al., Column 12, Lines 61-65).

h. In regard to Claim 13, West et al. further disclose “wherein the energy is electrical current having a frequency within the radio frequency (RF) range” (See West et al., Column 12, Lines 61-65).

i. In regard to Claim 14, the intended use/functional language “to ionize a conductive medium on top of a target tissue resulting in a low temperature molecular disintegration” carries limited patentable weight in the absence of any distinguishing structure. West et al. clearly discloses the claimed structure and is considered inherently capable of performing the intended use.

j. In regard to Claim 15, West et al. further disclose “wherein the functional tip is operable to deliver sufficient energy to the tissue to result in cell lysis” (See West et al., Column 12, Lines 61-65).

k. In regard to Claim 20, West et al. further disclose “wherein the functional tip comprises at least one active electrode” (See West et al., Figure 4, Reference 34; See also Column 8, Lines 24-27).

l. In regard to Claim 21, West et al. further disclose “wherein the functional tip comprises two or more electrodes” (See West et al., Figure 4, Reference 34; See also Column 8, Lines 24-27).

m. In regard to Claim 22, West et al. further disclose “wherein the electrodes are configured in an arrangement where at least one of the electrodes is active and at least one is a return electrode” (See West et al., Figure 4, Reference 34; See also Column 8, Lines 24-27). The functional language “configured in” carries limited patentable weight in the absence of any distinguishing structure.

West et al. clearly disclose two electrodes and is therefore considered by the examiner to be “configured in” an arrangement where one electrode is active and one is a return electrode.

n. In regard to Claim 23, West et al. further disclose “wherein the distal region comprises a distal portion and a proximal portion, the distal portion defining a straight shape and the proximal portion defining the curved shape” (See West et al., Figure 1A).

o. In regard to Claim 24, West et al. further disclose “wherein the distal portion defines a length of about 1 cm” and “wherein the proximal portion defines a length of about 6 cm and wherein the curved shape extends about 270 degrees of the circumference of a circle” (See West et al., Figure 1A). Although West et al. does not explicitly disclose the length of the distal portion, claimed lengths are considered to be within the scope of the device disclosed by West et al.

p. In regard to Claim 39, West et al. disclose “[A] device” comprising “an elongate member having a distal region and a proximal region” (See West et al., Figure 4, Reference 22; See also Column 8, Lines 22-23), “a functional tip at the distal region for delivering energy” (See West et al., Figure 4, Reference 34; See also Column 8, Lines 24-27), and “a control associated with the distal region and operable from the proximal region, wherein the control is operable to modify a shape of the distal region to direct the functional tip in a desired direction” (See West et al., Figure 4, References 40, 42, and 44; See also Column 12, Lines 48-60).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,545,200 to West et al. as applied to Claim 5 above and in view of U.S. Patent No. 6,635,222 to Edwards et al.

a. In regard to Claim 10, West et al. disclose "[A] device for creating a perforation" (See Claim 5 Rejection). West et al. does not meet the limitation "wherein the functional tip comprises a sharp tip." Edwards et al. teach an ablation tool "wherein the functional tip comprises a sharp tip" (See Edwards et al., Figure 8, Reference 24; See also Column 8, Lines 51-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a sharpened distal tip as taught by Edwards et al. on the device

disclosed by West et al. in order to facilitate easier insertion into the desired tissue treatment area.

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.

Patent No. 5,545,200 to West et al.

a. In regard to Claim 11, the selection of a known material based upon its suitability for its intended use is considered an obvious design consideration not patentably distinct over the prior art. (See MPEP, 2144.07).

6. Claims 16-19 and 26-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,545,200 to West et al. in view of U.S. Patent Application Publication No. US 2002/0087156 to Maguire et al.

a. In regard to Claim 16, West et al. disclose "[A] device" (See Claim 5 Rejection). West et al. do not meet the limitation "comprising a pressure sensing mechanism associated with the distal region for monitoring pressure about the distal region". Maguire et al. teach "a pressure sensing mechanism associated with the distal region for monitoring pressure about the distal region" (See Maguire et al., Paragraph [0288], Lines 1-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a pressure sensing mechanism associated with the distal region as taught by Maguire et al. on the device disclosed by West et al. in order to monitor pressure



about the distal region in order to establish/monitor position of the ablation catheter within the patient.

b. In regard to Claim 17, Maguire et al. further discloses “wherein the pressure sensing mechanism comprises a pressure transmitting lumen extending between the proximal and distal regions, the lumen adapted at the proximal region for fluid communication with a pressure transducer and adapted at the distal region for fluid communication with an environment about the distal region” (See Maguire et al., Paragraph [0288], Lines 1-10).

c. In regard to Claim 18, Maguire et al. further discloses “wherein the distal region defines at least one opening to the environment and wherein the lumen is in fluid communication with the at least one opening” (See Maguire et al., Paragraph [0288], Lines 1-10).

d. In regard to Claim 19, West et al. disclose “[A] device” (See Claims 5 and 16 Rejections). West et al. do not meet the limitation “wherein the pressure sensing mechanism comprises a pressure transducer on-board the distal region, the transducer being adapted for communication with a pressure monitoring system.” Maguire et al. teach “wherein the pressure sensing mechanism comprises a pressure transducer on-board the distal region, the transducer being adapted for communication with a pressure monitoring system” (See Maguire et al., Paragraph [0288], Lines 1-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a pressure transducer as taught by Maguire et al. on-board the distal region of the device

disclosed by West et al. in order to monitor pressure about the distal region in order to establish/monitor the position of the ablation catheter within the patient.

e. In regard to Claim 26, West et al. disclose “[A]n electrosurgical device comprising: an elongate member having a proximal region and a distal region” (See West et al., Figure 4, Reference 22; See also Column 8, Lines 22-23), “comprising a functional tip” (See West et al., Figure 4, Reference 34; See also Column 8, Lines 24-27), and “at least one electrode associated with the functional tip for cutting tissue” (See West et al., Figure 4, Reference 34; See also Column 8, Lines 24-27), “the at least one electrode adapted for coupling to an electrical energy source” (See West et al., Figure 4, Reference 34; See also Column 8, Lines 24-27). West et al. do not meet the limitation “a pressure sensing mechanism associated with the distal region for sensing pressure at a desired location within a patient, the mechanism adapted for coupling to a pressure monitoring system.” Maguire et al. teach “a pressure sensing mechanism associated with the distal region for sensing pressure at a desired location within a patient, the mechanism adapted for coupling to a pressure monitoring system” (See Maguire et al., Paragraph [0288], Lines 1-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a pressure sensing mechanism as taught by Maguire et al. on the device disclosed by West et al. in order to monitor pressure about the distal region in order to establish/monitor the position of the ablation catheter within the patient.

f. In regard to Claim 29, Maguire et al. further disclose “wherein the pressure sensing mechanism is configured to minimize a portion of the elongate member that is necessary to be located at the distal location to monitor pressure” (See Maguire et al., Paragraph [0288], Lines 1-10).

g. In regard to Claim 30, Maguire et al. further disclose “wherein the pressure sensing mechanism comprises a pressure transmitting lumen defined within the elongate member extending from the proximal region to couple to at least one opening defined in the distal region” (See Maguire et al., Paragraph [0288], Lines 1-10).

h. In regard to Claim 31, Maguire et al. further disclose “wherein the proximal region is adapted for coupling the pressure transmitting lumen to a pressure transducer associated with the pressure monitoring system” (See Maguire et al., Paragraph [0288], Lines 1-10).

i. In regard to Claim 32, Maguire et al. further disclose “wherein the pressure transmitting lumen is adapted for at least one of injecting a fluid to or removing a fluid from the patient” (See Maguire et al., Paragraph [0288], Lines 1-10). The claim language “adapted to” carries limited patentable weight in the absence of any distinguishing structure. Maguire et al. discloses a fluid filled pressure transmitting lumen with a distal opening and is considered inherently capable of the intended use.

- j. In regard to Claim 33, the recitation of “a coupling means extending through the pressure transmitting lumen” is considered an obvious design consideration not patentably distinct over the prior art.
  - k. In regard to Claim 34, see Claim 19 Rejection.
  - l. In regard to Claim 35, West et al. further disclose “wherein the at least one electrode defines a functional tip comprising a conductive and radiopaque material at the distal region” (See West et al., Figure 4, Reference 34; See also Column 8, Lines 24-27).
  - m. In regard to Claim 36, West et al. further disclose “wherein the electrical energy source is capable of providing high-frequency electrical energy to the functional tip in the high impedance range” (See West et al., Column 12, Lines 61-65).
  - n. In regard to Claim 37, Maguire et al. further disclose “wherein the proximal region is adapted to releasably couple the pressure sensing mechanism to the pressure monitoring system” (See Maguire et al., Figure 2A, Reference 212).
  - o. In regard to Claim 38, West et al. further disclose “wherein the proximal region is adapted to releasably couple the electrode to the electrical power source” (See West et al., Column 11, Lines 6-12).
7. Claims 40-43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,565,562 to Shah et al. in view of U.S. Patent No. 5,545,200 to West et al.

- a. In regard to Claim 40, Shah et al. disclose “[A] method of creating a perforation in a heart septum comprising: applying a form of energy to a perforation device positioned at a desired location of a heart septum to create a perforation at the desired location” (See Shah et al., Column 1, Lines 17-22; See also Column 2, Lines 19-22), “wherein the perforation device comprises an elongate member” (See Shah et al., Figure 1, Reference 7), and “advancing a distal tip of the device through, directing the distal tip in a desired direction” (See Shah et al., Column 7, Lines 19-22; the “desired direction” being the distal direction). Shah et al. do not explicitly meet the limitation “wherein the perforation device comprises a distal region capable of adopting a curved shape.” West et al. teach “wherein the perforation device comprises a distal region capable of adopting a curved shape” (See West et al., Figures 1, 3A, 3B, and 4). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a device with a distal region capable of adopting a curved shape as taught by West et al. for the method disclosed by Shah et al. in order to more easily steer the catheter to the desired treatment site.
- b. In regard to Claim 41, West et al. further disclose “wherein the perforation device comprises a control associated with the distal region and operable from the proximal region, wherein the control is operable to modify a shape of the distal region to direct the distal tip in a desired direction in relation to cardiac structures; and wherein the method comprises operating the control” (See West et al., Figure 4, References 40, 42, and 44; See also Column 12, Lines 48-60).

c. In regard to Claim 42, West et al. further disclose "wherein the method comprises manipulating the distal region to adopt the curved shape" (See West et al., Figure 4, References 40, 42, and 44; See also Column 12, Lines 48-60).

d. In regard to Claim 43, Shah et al. further disclose "wherein the distal tip is directed away from cardiac structures in order to decrease risk of unwanted injury". As broadly as claimed, Examiner concludes that when distal tip is directed at the septum it is "directed away from cardiac structures in order to decrease risk of unwanted injury".

e. In regard to Claim 45, West et al. further disclose "wherein the perforation device comprises an orientation indicator for determining a direction of the distal tip" (See West et al., Figure 4, References 40, 42, and 44). The method step of "monitoring the orientation indicator to advance the distal tip through the septum in a desired direction" is considered inherent in the operation of the device disclosed by West et al.

8. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,545,200 to West et al. in view of U.S. Patent No. 6,565,562 to Shah et al. as applied to Claim 40 above and in further view of U.S. Patent Application Publication No. US 2002/0087156 to Maguire et al.

a. In regard to Claim 44, Shah et al./West et al. disclose "[A] method of creating a perforation in a heart septum" (See Claim 40 Rejection). Neither Shah et al. nor West et al. disclose "wherein the perforation device comprises a

pressure sensing mechanism for sensing pressure at the distal tip and wherein the method comprises monitoring the pressure to indicate a location of the distal tip.” Maguire et al. teach wherein the perforation device comprises a pressure sensing mechanism for sensing pressure at the distal tip and wherein the method comprises monitoring the pressure to indicate a location of the distal tip” (See Maguire et al., Paragraph [0288]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a pressure sensing mechanism as taught by Maguire et al. on the device disclosed by West et al. in order to monitor the pressure to indicate a location of the distal tip.

### ***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Straighttiff whose telephone number is (571) 272-4774. The examiner can normally be reached on Monday through Friday 8:30 AM to 5:00 PM.

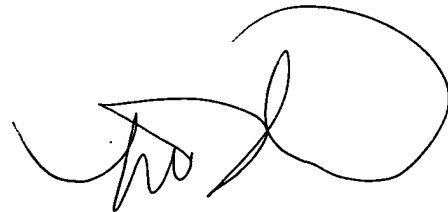
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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